U.S. Chamber of Commerce

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Via Regulations.gov

Dr. Lawrence Martin
EPA Docket Center
WJC West Building, Room 3334
1301 Constitution Avenue, NW
Washington, DC 20004

Re: U.S. Environmental Protection Agency Draft Cumulative Risk Assessment Guidelines for Planning and Problem Formulation (EPA-HQ-ODR-2013-0292)

Dear Dr. Martin:

The U.S. Chamber of Commerce ("Chamber") appreciates the opportunity to comment on the U.S. Environmental Protection Agency's ("EPA's" or "Agency's") Risk Assessment Forum *Draft Cumulative Risk Assessment (CRA) Guidelines for Planning and Problem Formulation* ("Draft CRA Guidelines" or "Guidelines").[1]

The Chamber is the world's largest business organization. Chamber members range from the small businesses and chambers of commerce across the country that support their communities to the leading industry associations and global corporations that innovate and solve the world's challenges to the emerging and fast-growing industries that are shaping the future. These industries include chemicals, coatings, refining, petrochemicals, petroleum, forestry, wood products, batteries, electronics, energy, electricity, and many others. These companies deliver products and innovation that are integral not only to the health and well-being of the American people but also to the domestic economy and supply chain. Chemical technologies improve our quality of life in numerous ways by providing new solutions to problems in health, materials, transportation, agriculture, and energy usage. Protecting the health of workers and surrounding communities is a priority for our members.

It is through this lens that we are providing comments on the Draft CRA Guidelines. As EPA attempts to refine its approach to CRAs that analyze, characterize, and possibly quantify the combined risks to health and/or the environment from multiple agents and/or stressors, it is important that these efforts are conducted consistent with the highest scientific standards that are transparent to the public and the regulated community, and in ways that are likely to withstand judicial scrutiny under the Administrative Procedure Act and other statutes. This is necessary to ensure appropriate protections for our workers, communities, and users of products, and to avoid unnecessary litigation risk for agency decisions. As EPA moves forward to finalize the Draft CRA Guidance, we ask that our comments and suggestions be considered.

[1] EPA, Risk Assessment Forum, *Draft Guidelines for Cumulative Risk Assessment Planning and Problem Formulation* (Draft CRA Guidelines), May 2023, available at: https://www.regulations.gov/document/EPA-HQ-ORD-2013-0292-0169.

The Importance of Planning and Problem Formulation in CRA

Planning and problem formulation is the most important part of a CRA. Providing a full understanding of the problem or question identified, and the boundaries of the intended investigation, is important not just to the CRA assessors but also to stakeholders that seek to engage with EPA as the CRA is developed. EPA's *Framework for Human Health Risk Assessment to Inform Decision Making*[2] is useful for assisting assessors in identifying issues to consider and questions to ask during planning and execution, and we support EPA's approach to continue to act consistently within this important framework.

As EPA finalizes these Guidelines, clarity on the scope, purpose, and data needs is paramount to help inform the design of the CRA. Attempting to address multiple, and potentially sequential, exposures, which may include chemical and non-chemical stressors, can very quickly become complex and unwieldly. The guidance should encourage assessors to recognize the limitations of the data available and how they can inform a fit-for-purpose assessment. A failure to focus on this step could lead to the development of a CRA that overstates conclusions based on what may end up being limited or low-quality data and information. If this or other steps in the process lead assessors to a conclusion that a CRA is not the correct approach for addressing a concern, consistent with the iterative process that the Draft CRA Guidelines suggests, the Guidelines should make clear that it is recommended that a different approach be used. Alternatively, as new data become available, EPA can revisit the CRA approach, allowing for the consideration of new data and information. Throughout the CRA process, as discussed in section 2.5 of the Draft CRA Guidelines, EPA must ensure that the level of analysis is commensurate with the risk decision it informs. Also, of course, EPA must also aways abide by the constraints on the scope and nature of its analyses that arise from the legal frameworks that govern particular analyses, as suggested in sections 2.2 and 2.4 of the Draft CRA Guidelines and in Appendix A.

EPA Must Rely on Best Available Science and Analytical Methods

Consistent with EPA's current practice, quantitative analysis relating stressor exposures to specific effects or changes in exposure-response relationships is necessary to support decisions on environmental and human health standards and regulations. In deciding whether to conduct a CRA, the Draft CRA Guidelines appropriately focus on suitability and feasibility.[3] In considering suitability, EPA's focus on the availability of data, adequate methods to analyze and integrate data, and resources needed to conduct the CRA is appropriate.[4] We agree that "poorly understood but suspected stressors or agents" may lead an assessor to deem that a "CRA approach would not be suitable."[5] The Guidelines should also clarify that this approach to suitability of a CRA must also be applied even if there is general interest in a community as to alleged stressors. Conducting a CRA without sufficient data and information will not benefit public interest and will not be fit for purpose if EPA is intending to use this information to inform risk management. We encourage EPA to ensure that data gaps are addressed in advance

[2] U.S. EPA. (2014). Framework for Human Health Risk Assessment to Inform Decision Making, Risk Assessment Forum, Office of the Science Advisor, available at: http://www2.epa.gov/osa/framework-human-health-risk-assessment-inform-decision-making.
[3] Draft CRA Guidelines at section 1.1.
[4] *Id.*
[5] *Id.*

of conducting a CRA. Problem formulation, as well as planning and scoping, can assist EPA in identifying data gaps and research needs.

When discussing feasibility, EPA states that "[a]dequate data must exist to inform the assessment with an acceptable level of uncertainty."[6] During planning and problem formulation, assessors should ensure that the "acceptable level of uncertainty" is well defined, and the Guidelines should recommend that this definition is made clear within the CRA. It is also important that the planning and problem formulation documents articulate the elements of the CRA for which uncertainty and variability will be discussed. Uncertainty and variability should be evaluated for all the major drivers of a CRA, including chemical and non-chemical stressors, exposure parameters, and demographics of the population of concern.

The evaluation of "perceived" stressors is one area where the guidance should stress greater attention to uncertainties.[7] Including "perceived" elevations in pollutant concentrations, or the perception of illness as initiating factors, will inappropriately strain limited EPA resources if perceptions are not supported by reliable data. While a CRA may be initiated based on community concerns, initiating factors should be supported by reliable data before a full CRA is conducted.

As EPA notes in section 2.4 of the Draft CRA Guidelines, methods for evaluating non-chemical stressors are complicated. Whether to consider these stressors as potential exposure-response modifiers at all is important. Even if EPA were to do so, EPA must develop appropriate methods and approaches for assessing and quantifying their impacts. The Guidelines should make clear that until such methods and guidance are developed, EPA should not include these non-chemical stressors in a CRA. Consideration of non-chemical stressors in a qualitative manner should also be discouraged in the Guidelines due to the large uncertainties that exist due to the current poor understanding of how these stressors interact with other well-defined stressors.

Consistent with ensuring that high quality data are used, EPA should be cautious when recommending that epidemiological studies and community observations be included in a CRA. If confounding factors in these studies are not appropriately controlled for and addressed, these studies may lead to spurious conclusions that are not representative of the populations EPA intends to evaluate. As EPA states, "[e]pidemiological studies, like any other source of information, should be used as sources of data only after careful consideration of their limitations and scope."[8]

Systematic review methods can also help to ensure that EPA's CRAs are of high quality and transparent. EPA's recommendation that the analysis plan include consideration of systematic review methods is appropriate and necessary. In addition to discussing the appropriateness of systematic review in the analysis plan, the Draft CRA Guidelines should also mention the importance of including weight of evidence ("WoE") approaches in the analysis plan. While WoE is discussed in section 3.7, the need to use WoE should also explicitly be included in the

[6] *Id.*
[7] *Id.* at section 2.1 where EPA includes "perceived stressors" as initiating factors.
[8] *Id.* at section 3.3.

discussion of the analysis plan (section 3.8).[9] EPA should also consider adding explicit language to the analysis plan section of the Guidelines that discusses the importance of the Bradford-Hill Criteria when evaluating causality.[10]

Finally, when discussing data quality, EPA must also ensure that the conceptual model for each CRA identify uncertainty and variability in the factors and endpoints that will be evaluated. While uncertainty and variability analyses are often the last section of many risk evaluations and are discussed in the near final section of the Draft CRA Guidelines, early consideration should be given to the approaches and methods that will be used to evaluate the uncertainties and variabilities in the CRA. Including these considerations in the conceptual model will help to ensure that uncertainties and variabilities are addressed throughout the CRA development process.

Tiering and Phasing of CRA Is Appropriate

The Draft CRA Guidelines acknowledge that tiering a CRA is an important planning method for targeting priority stressors and matching appropriate assessment efforts to the risk management decision. As EPA states, "[t]he intent of tiering or phasing the analysis is to tailor the level of effort to be commensurate with the purpose of the risk assessment."[11] While a tiered approach is appropriate, when a screening-level CRA identifies potential risks, before moving to risk management, EPA should replace conservative scenarios and assumptions used at the screening level with measured values and refine the CRA. When a potential regulatory action based on a CRA is economically significant, this becomes even more important. The CRA must be fit for purpose, and default values and conservative assumptions should be replaced with realistic estimates of exposure, ideally probabilistic estimates. Screening-level CRAs can be useful to help identify data gaps and areas for further research, but these results should not be used to inform regulations.

Stakeholder Engagement and Peer Review Is Essential

The Chamber and its members support robust stakeholder engagement and peer review practices. Peer review for CRAs should be consistent with EPA and OMB guidelines, and peer review plans should be posted on EPA's website allowing for sufficient time for stakeholders to comment on the plans. We also support robust stakeholder engagement that includes regulated entities in addition to communities and neighborhoods.

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[9] Section 3.8 of the Draft CRA Guidelines states: "Because sources of evidence might be available from multiple disciplines, the evaluation of the data required for a CRA should consider WoE both within and across evidence streams—e.g., epidemiology, toxicology, and mechanistic studies."

[10] See for example Fedak, K.M., Bernal A., Capshaw Z.A., Gross S. *Applying the Bradford Hill criteria in the 21st century: How data integration has changed causal inference in molecular epidemiology*. Emerg. Themes Epidemiol. 2015;12:14, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4589117/.

[11] Draft CRA Guidelines at section 1.2 and further discussed at section 2.5.

Thank you for the opportunity to provide these comments. The Chamber welcomes further discussion with EPA on this important draft guideline. Please contact Preston Beard, Director of Policy at pbeard@uschamber.com with any questions regarding these comments.

Sincerely,

Martin J. Durbin
Senior Vice President, Policy
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U.S. Chamber of Commerce